PTO/SB/52 (07-03)
Approved for use through 7/31/2003. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST FOR ACCESS TO AN ABANDONED APPLICATION UNDER 37 CFR 1.14

Bring completed form to:
File Information Unit
Crystal Plaza Three, Room 1D01
2021 South Clark Place
Arlington, VA
Telephone: (703) 308-2733

RECEIVED
MAR 28 2005
File Information Unit

In re Application of PLATZ ET AL

Application Number 08/246034 | Filed 8/29/02

Paper No. #19

I hereby request access under 37 CFR 1.14(a)(1)(iv) to the application file record of the above-identified ABANDONED application, which is identified in, or to which a benefit is claimed, in the following document (as shown in the attachment):

United States Patent Application Publication No. 6797258, page _____, line _____.

United States Patent Number _____, column _____, line, _____ or

WIPO Pub. No._____, page _____, line _____.

Related Information about Access to Pending Applications (37 CFR 1.14):

Direct access to pending applications is not available to the public but copies may be available and may be purchased from the Office of Public Records upon payment of the appropriate fee (37 CFR 1.19(b)), as follows:

For published applications that are still pending, a member of the public may obtain a copy of:
- the file contents;
- the pending application as originally filed; or
- any document in the file of the pending application.

For unpublished applications that are still pending:

(1) If the benefit of the pending application is claimed under 35 U.S.C. 119(e), 120, 121, or 365 in another application that has: (a) issued as a U.S. patent, or (b) published as a statutory invention registration, a U.S. patent application publication, or an international patent application publication in accordance with PCT Article 21(2), a member of the public may obtain a copy of:
- the file contents;
- the pending application as originally filed; or
- any document in the file of the pending application.

(2) If the application is incorporated by reference or otherwise identified in a U.S. patent, a statutory invention registration, a U.S. patent application publication, or an international patent application publication in accordance with PCT Article 21(2), a member of the public may obtain a copy of:
- the pending application as originally filed.

Eric Hable
Signature

3/28/05
Date

ERIC HABLE
Typed or printed name

Registration Number, if applicable

703-486-1150
Telephone Number

RECEIVED
FOR PTO USE ONLY
MAR 28 2005
Approved by: _____ (initials)
File Information Unit
Unit: _____

This collection of information is required by 37 CFR 1.14. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. BRING TO: File Information Unit, Crystal Plaza Three, Room 1D01, 2021 South Clark Place, Arlington, VA.

US006797258B2

(12) **United States Patent**
Platz et al.

(10) **Patent No.: US 6,797,258 B2**
(45) **Date of Patent: Sep. 28, 2004**

(54) **COMPOSITIONS AND METHODS FOR THE PULMONARY DELIVERY OF AEROSOLIZED MACROMOLECULES**

(75) Inventors: **Robert M. Platz**, Half Moon Bay, CA (US); **John S. Patton**, Portola Valley, CA (US); **Linda Foster**, Sunnyvale, CA (US); **Mohammed Eljamal**, Tripoli, CA (US)

(73) Assignee: **Nektar Therapeutics**, San Carlos, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/072,430**

(22) Filed: **Feb. 8, 2002**

(65) **Prior Publication Data**

US 2002/0117170 A1 Aug. 29, 2002

Related U.S. Application Data

(63) Continuation of application No. 08/423,515, filed on Apr. 14, 1995, and a continuation-in-part of application No. 08/417,507, filed on Apr. 4, 1995, now abandoned, and a continuation-in-part of application No. 08/383,475, filed on Feb. 1, 1995, now abandoned, which is a continuation-in-part of application No. 08/232,849, filed on Apr. 25, 1994, now Pat. No. 5,607,915, and a continuation-in-part of application No. 08/313,707, filed on Sep. 27, 1994, now abandoned, and a continuation-in-part of application No. 08/309,691, filed on Sep. 21, 1994, now Pat. No. 5,785,049, and a continuation-in-part of application No. 08/246,034, filed on May 18, 1994, now abandoned, which is a continuation of application No. 08/044,358, filed on Apr. 7, 1993, now abandoned, which is a continuation-in-part of application No. 07/910,048, filed on Jul. 8, 1992, now Pat. No. 5,458,135.

(51) **Int. Cl.**[7] **A61K 9/00**; A61K 9/12; A61K 9/14

(52) **U.S. Cl.** **424/45**; 424/46; 424/489; 424/499; 514/15; 514/17; 514/2; 128/200.14

(58) **Field of Search** 424/45, 46, 489, 424/499; 514/15, 17, 2, 18; 128/200.14

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,598,525	A	5/1952	Fox
3,202,731	A	8/1965	Grevenstuk et al.
3,300,474	A	1/1967	Flodin et al.
3,314,803	A	4/1967	Tarrytown et al.
3,362,405	A	1/1968	Hazel
3,425,600	A	2/1969	Abplanalp
3,540,927	A	11/1970	Numi et al.
3,554,768	A	1/1971	Feldman
3,594,476	A	7/1971	Merril
3,608,066	A	9/1971	Illartein
3,620,776	A	11/1971	Mishkin et al.
3,666,496	A	5/1972	Honey et al.
3,674,901	A	7/1972	Sheperd et al.
3,764,716	A	10/1973	Rainwater et al.
3,921,637	A	11/1975	Bennie et al.
3,964,483	A	6/1976	Mathes
3,971,852	A	7/1976	Brenner et al.
3,991,304	A	11/1976	Hillsman
3,991,761	A	11/1976	Cocozza
3,994,421	A	11/1976	Hansen
4,036,223	A	7/1977	Obert
4,069,819	A	1/1978	Valentini et al.
4,098,273	A	7/1978	Glenn
4,105,027	A	8/1978	Lundquist
4,109,019	A	8/1978	Moore
4,153,689	A	5/1979	Hiral et al.
4,192,309	A	3/1980	Poulsen
4,206,200	A	6/1980	Guthohrlein et al.
4,211,769	A	7/1980	Okada et al.
4,227,522	A	10/1980	Carris
4,249,526	A	2/1981	Dean et al.
4,253,468	A	3/1981	Lehmbeck
4,294,624	A	10/1981	Veltman
4,294,829	A	10/1981	Suzuki et al.
4,338,931	A	7/1982	Cavazza
4,423,079	A	12/1983	Kline
4,446,862	A	5/1984	Baum et al.
4,452,239	A	6/1984	Malem
4,484,577	A	11/1984	Sackner et al.

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

BE	902257	8/1985
DE	1812574	6/1970
DE	2415159	10/1975
DE	3141498	4/1983
DE	0161072	9/1984
EP	0015123	9/1980

(List continued on next page.)

OTHER PUBLICATIONS

US 5,849,884, 12/1998, Woiszwillo et al. (withdrawn)
E.L. Andrews, "Gelatin Capsules Revamped for New Generation of Pills," New York Times, Saturday, Sep. 16, 1992, 19 (N), 35 (L), col. 5, 9 col. in.
D.I. Annear, "Observations on Drying Bacteria from the Frozen and from the Liquid State," Austral. J. Exp. Biol., 1958, vol. 36, p. 211–221.

(List continued on next page.)

Primary Examiner—Thurman K. Page
Assistant Examiner—Mina Haghighatian
(74) *Attorney, Agent, or Firm*—Mark A. Wilson; Susan T. Evans

(57) **ABSTRACT**

According to the subject invention, dispersible dry powder pharmaceutical-based compositions are provided, including methods for their manufacture and dry powder dispersion devices. A dispersible dry powder pharmaceutical-based composition is one having a moisture content of less than about 10% by weight (% w) water, usually below about 5% w and preferably less than about 3% w; a particle size of about 1.0–5.0 μm mass median diameter (MMD), usually 1.0–4.0 μm MMD, and preferably 1.0–3.0 μm MMD; a delivered dose of about >30%, usually >40%, preferably >50%, and most preferred >60%; and an aerosol particle size distribution of about 1.0–5.0 μm mass median aerodynamic diameter (MMAD), usually 1.5–4.5 μm MMAD, and preferably 1.5–4.0 μm MMAD. Such compositions are of pharmaceutical grade purity.

22 Claims, No Drawings